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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/160,618 09/24/98 CHRISTENSEN

E 73690

EXAMINER

HM12/0705

WELSH & KATZ
120 SOUTH RIVERSIDE PLAZA
CHICAGO IL 60606-3913

WARE, T

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/160,618

Applicant(s)

CHRISTENSEN, EDWIN H.

Examiner

Todd D Ware

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 April 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 9-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5, 9-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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DETAILED ACTION

Receipt of amendment filed 4-23-01 is acknowledged. Claims 1, 12, and 26 have been amended as requested.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-5, 9-11, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Yang et al (4,882,153; hereafter '153).

'153 discloses confectionery delivery systems comprising an extruded matrix having a range of a sweetener that is a mixture of sorbitol, starch, and sugar that encompasses the ranges and amounts of the instant claims along with about 1-30% water. '153 also discloses active agents such as aspirin and mineral supplements. '153 does not specifically list the water activity of the formulations, however, given that the percentages of the ingredients appear to be the same as that of the instant claims, it is submitted that the claimed water activity would be inherent within '153.

Response to Arguments

3. Applicant's arguments filed 4-23-01 have been fully considered but they are not persuasive. Applicant argues that since claim 1 recites "the A_w is adjusted to permit an appropriate amount of free water in the presence of the additive" it is distinguished over

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'153. However, this is a process limitation and is not afforded patentable weight.

Moreover, '153 discloses water in amounts within applicant's ranges.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 1-5, 9-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang et al (4,882,153; hereafter '153).

'153 discloses confectionery delivery systems comprising an extruded matrix having a range of a sweetener that is a mixture of sorbitol, starch, and sugar that encompasses the ranges and amounts of the instant claims along with about 1-30% water. '153 also discloses active agents such as aspirin and mineral supplements.

'153 does not specifically list the exact amounts of ingredients as the instant claim (e.g. '153 does not list a starch content of about 32%), nor does '153 specifically list the water activity of the formulations. However, the ranges provided in '153 encompass the specific amounts of the instant claims and it is submitted that these amounts are manipulatable parameters that would be obvious to one skilled in the art at the time of the invention to adjust to obtain a chewable dosage form. Furthermore, given that the percentages of the ingredients appear to be the same as that of the

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instant claims, it is submitted that the claimed water activity would be inherent within '153.

'153 also does not state that the matrix is mixed in a one-step procedure. However it is submitted that it would have been obvious to one skilled in the art at the time of the invention that the pre-coating step of '153 would not be necessary in the event where the active agent is not bitter. Furthermore, this step does not appear to be critical, since page 6, lines 4-5 of the instant specification indicates that antibitterness agents and taste masking agents may be added to the instant composition/method.

Response to Arguments

6. Applicant's arguments filed 4-23-01 have been fully considered but they are not persuasive. Applicant argues that since claim 1 recites "the A_w is adjusted to permit an appropriate amount of free water in the presence of the additive" it is distinguished over '153. However, this is a process limitation and is not afforded patentable weight. Moreover, '153 discloses water in amounts within applicant's ranges.

Applicant further argues that since the method claims are require a one-step procedure for forming the matrix, the method claims are distinguished over '153. However, as stated in the rejection under 35 U.S.C. 103(a), while '153 does not state that the matrix is mixed in a one-step procedure, it would have been obvious to one skilled in the art at the time of the invention that the pre-coating step of '153 would not be necessary in the event where the active agent is not bitter. Furthermore, this step does not appear to be critical, since page 6, lines 4-5 of the instant specification

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indicates that antibitterness agents and taste masking agents may be added to the instant composition/method.

Applicant has also amended the instant claims to recite sucrose, submitting that '153 is directed to a fat free and sucrose free composition. However, disclosure of inclusion of several sugars in column 7, lines 7-22, demonstrates that this is merely an embodiment of '153.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Todd D Ware whose telephone number is (703) 305-1700. The examiner can normally be reached on 7:30 AM - 4 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703)308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

tw
June 29, 2001